



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 22, 2011

To: Enforcement Committee

Subject: Agenda Item 1- Exemptions Requested from Patient-Centered Labeling Requirements

On January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5. A copy of the final text for the regulation follows this page.

Also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments.

To allow such an exemption, the board will need to promulgate regulations.

At this meeting, the board will hear presentations from three groups seeking an exemption from the labeling requirements for their specialized patient populations. Medco, which had previously requested an exemption for the labeling of infusion products (and had provided presentations at the last Enforcement Committee and February Board Meeting), has withdrawn its request.

The board will need to determine whether it wishes to exempt from the patient-centered label requirements the specific drug products or the medications dispensed in any of these environments.

The full amendment to section 4076.5 contained in SB 1489 is provided following the board's new patient-centered label requirements (section 1707.5). The last document is the full text of Health and Safety Code section 1250.

1. For Pharmacies Making Total Parenteral Therapy (TPN):

A representative of Walgreens will provide a presentation requesting an exemption from labeling requirements for TPN products. Walgreens has been asked to demonstrate how they can provide appropriate consumer protection and information without the patient-centered labels. A request from Walgreens for this

The specific possible exemption for infusion pharmacies occurs in Business and Professions Code section 4076.5(e) (effective 1/1/11):

- (e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
 - (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
 - (B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
 - (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
 - (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
- (2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

2. Request from CPhA's Long-Term Care Academy

Representatives of CPhA will attend this meeting to explain how patient safety in long-term care facilities can be ensured without patient-centered labels. At the February Board Meeting, CPhA was asked to return to the next Enforcement Committee Meeting and provide additional information

The relevant section to authorize such an exemption occurs in section 4076.5(d):

- (d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

A list of the entities licensed under Health and Safety Code Section 1250 (and the relevant subdivision number) is:

1. General acute care hospital (a)
2. Acute psychiatric hospital (b)
3. Skilled nursing facility (c)
4. Intermediate care facility (d)
5. Intermediate care facility/developmentally disabled habilitative (e)
6. Special hospital (f)
7. Intermediate care facility/developmentally disabled (g)
8. Intermediate care facility/developmentally disabled-nursing (h)
9. Congregate living health facility (i)
10. Correctional treatment center (j)
11. Nursing facility (k)
12. Intermediate care facility/developmentally disabled-continuous nursing (m)

3. From GE Healthcare for Radiopharmaceuticals

A representative of GE Healthcare will request an exemption from the patient-centered labeling requirements for radiopharmaceuticals. Again, GE Healthcare has been asked to demonstrate how they can provide appropriate consumer protection and information without the patient-centered labels.

Background materials follow this page that have been submitted from GE Healthcare.

January 18, 2011

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Dear Ms. Herold,

Walgreens requests to be placed on the next applicable committee or Full Board meeting. We are seeking an exemption of our Walgreen Home Care TPN label from Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations. Our patients are provided a thorough training on TPN administration by a healthcare professional and have detailed labels that are difficult to place in the proper format and font. Due to these special circumstances, we would like to appear before the Board to present this request.

Thank you for considering this exemption and I look forward to meeting with the Board at the next meeting.

Please call me if you have any questions.

Sincerely,



Al Carter, Pharm.D.
Manager, Pharmacy Affairs
Walgreen Co.
200 Wilmot Rd.
Deerfield, IL 60015
Phone 847-914-3940
Fax 847-914-3109
Al.Carter@Walgreens.com

Cc: Mike Simko

T.P.N. LABEL

Caution: Federal and/or State Law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.

WALGREENS INFUSION SERVICES091 800-400-9422
12107 Los Nietos Suite 7 800-400-9422
Santa Fe Springs, CA 90670-2539

Rx #: T27C32 Prescriber 1: William Welsh,
Disp Date: 01/06/2011 Prescriber 2:

Route: IV-Intravenous - Central

Name: Daniel [REDACTED] HT: 70 in WT: 170 lb DOB: 03/29/[REDACTED]
[REDACTED] Fultori Wells Avenue, [REDACTED] Santa Fe Springs, CA 90670

Item	Generic For	Mfg	Dose
TRAVASOL		00338	97.5 Gm
DEXTROSE		00338	390 Gm
INTRALIPID		00338	48 Gm
WATER FOR INJECTION		00338	314.49 ml
POTASSIUM CHLORIDE		00264	52 mEq
SODIUM CHLORIDE		00409	58.5 mEq
MAGNESIUM SULFATE		00409	32 mEq
CALCIUM GLUCONATE		00517	10 mEq
SODIUM PHOSPHATE		00517	32mEqNa;24 mMolPhos
SODIUM ACETATE		00409	39 mEq
SELENIUM		00517	78 mcg
CHROMIUM		00409	15.6 mcg
<u>Patient Adds:</u>			
INFLUVITE		00338	10 ml / 10 ml

Dosage: TPN 3:1 2240MLAA67.5gm//DEX390gm// LIPIDS 48gm

Infuse: Infuse 2190ml intravenously via central IV line & Cadd pump over 14hrs 5days/week. Add 10ml MVI prior to use

Pump Settings: Res Vol: 2240// Inf Vol: 2190//

Cycle: 14hrs// Taper up/Down: 1hr

Storage: Refrigerate: Remove from fridge 1 hr prior to infusion

Na: 128.52 mEq/Bag K: 52 mEq/Bag Cl: 149.52 mEq/Bag

Ca: 10 mEq/Bag Mg: 31.99 mEq/Bag Ac: 123.83 mEq/Bag

Phos: 24 mMol/Bag

Fat Cal: 480 kCal CHO Cal: 1325.99 kCal Protein: 97.5 Gm

Total Non-Protein KCal: 1805.99kCal

OverFill: 60 ml Infusion Volume: 2190 ml Total Volume: 2250 ml

Taper Up: 60min Taper Down: 60 min Infusion Period: 14 hrs

Discard After: 01/14/2011 Qty Disp: 5 Refills Left: 95

Entered By: showard Checked By: _____

Discard any unused volume after 24 hours.

Caution: Federal and/or State Law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.



GE Healthcare

Richard Hughes
Corporate Radiation Safety Officer
101 Carnegie Center
Princeton, NJ 08540

O - 609-514-6647
C - 609-209-6832
F - 215-827-5702
rick.hughes@gc.com

5 October 2010

Debbie Anderson
Director of Licensing
State Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

Re: Request for letter of interpretation on proposed Title 16 section 1707.5 Patient-Centered Labels on Medication Containers

Ms. Anderson:

The intent of this letter is for further interpretation of the proposed Title 16 section 1707.5 Patient-Centered Labels on Medication. GE HealthCare recognizes section 1707.5 is not final. This is a preemptive request for interpretation to ensure compliance on the day of implementation, as California Business and Professions Code section 4076.5 mandates the requirement to be in effect on or before January 2011.

Title 16 section 1707.5 states "Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient centeredness."

Pursuant to a telephone conversation on September 30, 2010 to your office, Medi-Physics, Inc. dba GE Healthcare explained that the regulation would not apply because Medi-Physics, Inc. dba GE Healthcare is a licensed Nuclear Pharmacy that dispenses patient specific unit dose radiopharmaceutical prescriptions, and bulk radiopharmaceutical products to other radioactive materials licensees authorized to use these products. We do not distribute our products to the general public, nor directly to the patient.

Each authorized licensee must possess a radioactive materials license (RAML) from the California Radiologic Health Branch (RHB) or Nuclear Regulatory Commission (NRC) in which to order and receive radio-pharmaceuticals. Attachment A contains a copy of our Anaheim RAML. This license is representative of a typical RAML held by our California based facilities. Please refer to condition 23 and 25 stating GE Healthcare is not allowed to distribute products to unauthorized agents.

All prescriptions dispensed by GE Healthcare facilities are distributed to, received and are administered by licensed Health Care Professionals only (i.e. RHB and/ or NRC Authorized Physician, or Certified Nuclear Medicine Technologist). Attachment B contains examples of container labels that are currently used by GE HealthCare radio-pharmacies.

Should you require any additional information regarding this request for a letter of interpretation please feel free to contact Rick Hughes 609.514.6647 or at Rick.Hughes@gc.com. Thank you in advance for your assistance in this matter.

Regards,

A handwritten signature in black ink, appearing to read 'Richard A. Hughes', written over a large, stylized flourish.

Richard A. Hughes
Director of Pharmacy Regulatory Assurance

ATTACHMENT A
ANAHEIM RAML#4810-30

PLUP: THANK-YOU
ACT: 946236 01

OCTOBER 5, 2010

PAGE 1

***** RETURN GOODS AUTHORIZATION *****

TO: GE HEALTH CARE
10 COMMERCE WAY
SUITE A

RGA NBR
RG2419140

RETURN TO: FISHER SCIENTIFIC COMPANY
NORTHEAST DISTRIBUTION CE
325 BOWLES ROAD

AGAWAM MA 01001

WOBURN MA 01801
ATTN: BOHN, ANTHONY A/-

EXPIRE DATE
JANUARY 3, 2011

REP: JULIE BAPTIE
PHONE: (630)259-1200

PO NUMBER: 305805505/CR
REF NUMBER:

ORDER NBR: D02747892

PLEASE ACCEPT THIS FORM AS YOUR AUTHORIZATION FOR RETURNING THE LISTED PRODUCT(S) PER YOUR REQUEST. WHEN PREPARING THE ITEMS(S) FOR RETURN, PLEASE COMPLY WITH THE FOLLOWING INSTRUCTIONS:

1. ENCLOSE THIS FORM WITH THE SHIPMENT AS THE PACKING SLIP.
2. PACK ALL RETURNS CAREFULLY WITH PROPER PROTECTION FOR EACH ITEM. REFURBISHING CHARGES CAN BE ELIMINATED WITH CAREFUL PACKING. FISHER SCIENTIFIC IS NOT RESPONSIBLE FOR GOODS DAMAGED IN RETURN SHIPMENT
3. RETURN HAZARDOUS MATERIALS IN ACCORDANCE WITH APPLICABLE DEPARTMENT OF TRANSPORTATION REGULATIONS.
4. FISHER SCIENTIFIC, UNDER FEDERAL REGULATIONS, IS NOT PERMITTED TO RECEIVE HAZARDOUS WASTE.
5. SHIP TRANSPORTATION PREPAID.

QTY	QUANT	UNIT	CATALOG NBR	DESCRIPTION	RCN
1	1	EA	BP671 10	BOVIN SER ALB LYOPH PWDR 10G	001

TELL US ABOUT YOUR RECENT CUSTOMER-SERVICE EXPERIENCE BY COMPLETING A SHORT SURVEY. THIS SHOULD TAKE NO LONGER THAN THREE MINUTES. ENTER THE LINK INTO YOUR BROWSER: <http://survey.medallia.com/fishersci> PASSCODE: USA-PGH-CS1

----- PART OF THERMO FISHER SCIENTIFIC -----
----- PART OF THERMO FISHER SCIENTIFIC -----

05/28/2010 14:10 9163220639

RADIOLOGIC HEALTH BR

PAGE 02/07

State of California-Health and Human Services Agency

California Department of Public Health

Page 1 of 6 pages

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the California Department of Public Health now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee:	Medi-Physics, Inc. dba GE Healthcare	3. License Number:	4810-30	Amendment Number:	46
2. Address:	150 West Cerritos Avenue, Suite 150 Anaheim, CA 92805	4. Expiration date:	January 16, 2004	(2)	
Attention:	Norihiko Morikawa, R.Ph. Radiation Safety Officer	5. Inspection agency:	Radiologic Health Branch South		

License Number 4810-30 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A.	A. Any	A.
1. Any radionuclide with atomic numbers 3-83 inclusive, except: Strontium-90, Lead-210 and the radionuclides specifically listed below:		1. Total not to exceed 6 Ci. no single nuclide to exceed 3.5 Ci.
2. Rubidium-81		2.-3. Total not to exceed 500 mCi.
3. Krypton-81m		
4. Molybdenum-99		4.-5. Total not to exceed 201 Ci.
5. Technetium-99m		
6. Iodine-123		6. Total not to exceed 2.5 Ci.
7. Iodine-125		7. Total not to exceed 2 Ci.
8. Iodine-129		8. Total not to exceed 500 mCi.
9. Iodine-131		9. Total not to exceed 3 Ci.
10. Xenon-133		10. Total not to exceed 5 Ci.
11. Xenon-127		11. Total not to exceed 2 Ci.

State of California-Health and Human Services Agency

California Department of Public Health

Page 2 of 6 pages

RADIOACTIVE MATERIAL LICENSE

License Number: 4810-30

Amendment Number: 46

6. Nuclide	7. Form	8. Possession Limit
B. 1. Iodine-125 2. Palladium-103	B. Seeds for Brnchtherapy	B. 1.- 2. Total not to exceed 5 Ci. Each seed not to exceed 1 mCi.
C. Any radionuclide with atomic numbers 3-83 inclusive; except: Strontium-90 and Lead-210.	C. Prepackaged units for <u>in vitro</u> diagnostic test kits.	C. Total not to exceed 5 mCi, each radionuclide not to exceed 1 mCi.
D. Any radionuclide with atomic number 3-83 inclusive.	D. Any sealed sources manufactured, labeled, packaged and in distributed in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.	D. Total not to exceed 5.0 Ci, no single source to exceed 200 mCi.
E. Depleted Uranium	E. Metal	E. Total not to exceed 400 kilogram (135 mCi).
F. Any radionuclide with atomic number 3-83 inclusive.	F. Analytical Wipe Tests	F. Total not to exceed 5 μ Ci.

9. Authorized Use

- A. Preparation and distribution of radioactive drugs including compounding of Iodine-123, 125 and 131 and redistribution of used and unused Molybdenum-99/Technetium-99m and Rubidium-81/Krypton-81m generators to authorized recipients in accordance with the California Code of Regulations, Title 17, Section 30210.2. Preparation and distribution of radioactive drugs and radiochemicals including compounding of Iodine-123, 125, and I-131 and redistribution of used and unused Molybdenum-99/ Technetium-99m and Rubidium-81/Krypton-81m generators to authorized recipients for non-medical use.
- B. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 or equivalent Agreement State or Licensing State requirements. Redistribution of sealed sources that have been registered either with U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State or a Licensing State and have been distributed to persons specifically authorized by U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive, possess and use the devices/sources.
- C. Redistribution to specific licensees or general licensees in accordance with title 17, California Code of Regulations, Section 30192.5 provided the packaging and labeling remain unchanged.

State of California-Health and Human Services Agency

California Department of Public Health

Page 3 of 6 pages

RADIOACTIVE MATERIAL LICENSELicense Number: 4810-30Amendment Number: 46

- D. Calibration and checking of the licensee's instruments and provide quality assurance testing to persons licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. Redistribution of sealed source initially distributed by a manufacturer licensed pursuant to 10 CFR 21.74 or equivalent Agreement State or Licensing State requirements to authorized recipients for medical or non medical use.
- E. To be used in shielding for Molybdenum-99/Technetium-99m and Rubidium-81/Krypton-81m generators.
- F. To be used incidental to analysis of wipe test samples as a customer service.

LICENSE CONDITIONS

- 10. Radioactive material shall be used only at the following location:
 - (a) 150 West Cerritos Avenue, Suite 150, Anaheim, CA.
- 11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.
- 12. Radioactive material shall be used by, or under the supervision and in the physical presence of, the following individuals:
 - (a) Robert Irwin, R.Ph.
 - (b) Norihiko Morikawa, R.Ph.
 - (c) Randy Kohen, R.Ph.
 - (d) Don Tran Nguyen, R.Ph.
 - (e) Paul Nguyen, Pharm.D.
 - (f) Any other radiopharmacist, registered by the California State Board of Pharmacy, and also listed on a specific license of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State for a maximum period of sixty days.
- 13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - (a) The license renewal application with attachments dated March 16, 1994, signed by Karl Nigg, Vice President of Pharmacies, as modified by the letter received March 6, 1995, and letter with attachments dated March 10, 1995, both signed by Paula C. Jeter, Sr. Health Physicist, Regulatory Affairs.
 - (b) The letter dated October 22, 1996, signed by Randy R. Kohen, R.Ph., Radiation Safety Officer, regarding addition of chemical grade Iodine-123.
 - (c) The letter dated February 6, 1997, with attachments, signed by Randy R. Kohen, R.Ph., Facility Manager, Radiation Safety Officer, regarding the remodeled floor plan and new area wipe map.
 - (d) The letter, with attachment, dated January 25, 2001, signed by Richard A. Hughes, Corporate Radiation Safety Officer, regarding revisions in the packaging and transport procedures.

State of California-Health and Human Services Agency

California Department of Public Health

Page 4 of 6 pages

RADIOACTIVE MATERIAL LICENSELicense Number 4810-30Amendment Number: 46

- (e) The letter dated November 20, 2000, the letter dated June 18, 2001, and the letter dated June 29, 2001, all signed by Richard A. Hughes, Corporate Radiation Safety Officer, regarding the redistribution of sealed brachytherapy sources.
 - (f) The letter, with attached diagram, dated December 14, 2001, signed by Randy R. Kohon, R. Ph., Facility Manager, as supplemented by the letter, with attachments, dated February 5, 2002, signed by Richard Hughes, Corporate Radiation Safety Officer regarding the 150 West Cerritos Avenue, Suite 150, use location.
 - (g) The letters, all with attachments, dated August 19, 2002, October 3, 2002 and December 2, 2002, all signed by Richard A. Hughes, Corporate Radiation Safety Officer, regarding the removal of the 1341 Gene Autry Way, Anaheim, CA use location from license.
 - (g) The letter, with attachment, dated March 19, 2003, signed by Richard A. Hughes, Corporate Radiation Safety Officer, regarding the appointment of a Corporate Radiation Safety Officer.
 - (h) The letter, with attachments, dated May 14, 2004, signed by Richard A. Hughes, Corporate Radiation Safety Officer, regarding a change in ownership.
 - (i) The letter, with attachment, dated August 9, 2007, and the letter, with attachments, dated September 3, 2007, both signed by Richard A. Hughes, Corporate Radiation Safety Officer, regarding the request to provide wipe test analysis as a customer service and new pharmacy labels.
 - (j) The letter, with attachments, dated June 6, 2008, signed by Richard A. Hughes, Corporate Radiation Safety Officer, regarding modifications to the fume hood for the Capsulator.
 - (k) The letter, with attachments, dated April 6, 2009, signed by Norihiko Morikawa, R.Ph., Radiation Safety Officer, regarding replacement of Appendix G, "Product Shielding and Radiation Measurements", in the license application dated November 29, 2003.
 - (l) The letters, with attachments, dated April 12, 2010, and May 10, 2010, both signed by Richard A. Hughes, Corporate Radiation Safety Officer, and the letter, with attachment, dated May 27, 2010, signed by Nori Morikawa, R.Ph., Radiation Safety Officer, regarding the remodeling of the restricted area, with associated commitments and procedures.
14. (a) The Corporate Radiation Safety Officer shall be Richard A. Hughes.
 (b) The Radiation Safety Officer in this program shall be Norihiko Morikawa, R.Ph.
15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (c).
16. In lieu of the leak test intervals required by California Code of Regulations, Title 17, Section 30275 (c), sealed sources can be tested for leakage and/or contamination at longer intervals when they are specified in a certificate of registration issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. When a longer interval stipulated in a certificate of registration is used, the certificate must be maintained on file and available for inspection for as long as the associated leak test records are retained.

State of California-Health and Human Services Agency

California Department of Public Health

Page 5 of 6 pages

RADIOACTIVE MATERIAL LICENSELicense Number: 4810-30Amendment Number: 46

17. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Public Health:
 - (a) The Radiation Safety Officer
 - (b) Qualified individuals designated in writing by the Radiation Safety Officer
18. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.
19. The licensee shall comply with all requirements of Title 17, California Code of Regulations, Section 30373 when transporting or delivering radioactive materials to a carrier for shipment. These requirements include: packaging, marking, labeling, loading, storage, placarding, monitoring, and accident reporting. Shipping papers shall be maintained for inspection pursuant to the U.S. Department of Transportation requirements (Title 49, Code of Federal Regulations, Part 172, Sections 172.200 through 172.204).
20. The licensee may use one constancy source for the dose calibrator constancy test provided that the dose calibrator manual indicates that only one constancy source is needed for proper Quality Control.
21. The licensee may use any commercially available device, acceptable to the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, for doing linearity tests of its dose calibrator provided the procedures described by the manufacturer of the linearity device are followed.
22. The licensee is authorized to perform nuclear medicine equipment quality assurance tests as a customer service using equipment and procedures in accordance with the statements, procedures and representations in Condition 13 of this license.
23. Reagent kits may be redistributed to persons pursuant to Title 17, California Code of Regulations, Section 30195 9a) and (b), or a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.
24. Vials containing Xenon-133 gas manufactured, labeled and packaged for pharmaceutical use, may be redistributed to persons licensed pursuant to Title 17, California Code of Regulations, Section 30195 (n) and (b), or a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, in accordance with the statement, procedures and representations in Condition 13 of this license.
25. Radiopharmaceuticals may be redistributed to persons licensed pursuant to, Title 17, California Code of Regulations, Section 30195 (a) and (b), or a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State in accordance with the statements, procedures and representations in Condition 13 of this license.
26. The licensee is hereby granted authorization to retrieve radioactive waste from customers facilities in accordance with the procedures described in Condition 13 of this license. Collection of radioactive waste from customer facilities shall be limited to waste generated from materials supplied under conditions of this license.
27. Where users or their assistants are engaged in elution of pertechnetate 99m from generators, the exposure to the fingers or hands shall be monitored as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (a).

State of California-Health and Human Services Agency

California Department of Public Health

Page 6 of 6 pages

RADIOACTIVE MATERIAL LICENSE

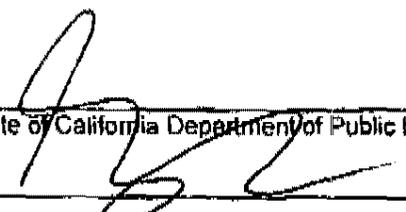
License Number: 4810-30Amendment Number: 46

28. Equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in vitro assay samples, shall be calibrated to ensure the reliability of data obtained. The stability of the equipment shall be checked at least once on each day of use, using appropriate standards.
29. The licensee is authorized to hold radioactive materials with a physical half-life of less than 65 days for decay in storage before disposal in ordinary trash provided:
- (a) Radioactive waste to be disposed of in this manner shall be held for decay in storage for at least 10 half-lives.
 - (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - (c) Records shall be maintained of the disposal of licensed materials made by decay in storage. These records shall be sufficient to demonstrate compliance with this license condition and shall be retained for 3 years after the record is made.
 - (d) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
30. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material so that at no time will the total quantity of radioactive material possessed require financial surety for decommissioning in accordance with the California Code of Regulations, Title 17, Section 30195.1. A value of 100 microcuries is assigned to Cobalt-57 to supplement the Code of Federal Regulations, Title 10, Part 30, Appendix B.
31. The licensee will provide the Low Level Radioactive Waste (LLRW) reports specified in the California Health and Safety Code section 115000.1(h) to the California Department of Public Health (CDPH) on an annual basis for both shipped and stored LLRW. Alternatively, LLRW shipment information may be provided on a per shipment basis. LLRW shipment information and annual reports shall be mailed to:

Attn: LLRW Tracking Program
California Department of Public Health
Radiologic Health Branch MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414

32. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 150 West Cerritos Avenue, Suite 150, Anaheim, CA.

Issued for the State of California Department of Public Health

Date: May 28, 2010By: 

Radiologic Health Branch, MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414

ATTACHMENT B
EXAMPLE PERSCRIPTION LABELS

GE Healthcare Boston
20 Commerce Way
Woburn, MA, 01801
T: 781-932-4200
FAX: 781-932-4200
Old Road to Nine Acre Corner, CONCORD, MA2, 01742 MA1-047

Wed 10/6/2010

Order# 1747099 RX# 1709510

EMERSON HOSPITAL
Nuclear Medicine
Myocardial Perfusion
PT: Mackay, B 11/5/30

Tc-99m Myoview (tetrofosmin)
28.0000 mCi @ 11:00 On 10/6/2010
1.0224 ml (cc)

DR: [REDACTED]
Connaughton, M.D.

Mo-99 content < 0.15 uCi/mCi at expiration time

Imaging Set / Dose by
Control # 37-10/6/2010
ACT DISP: 28.00 mCi (11,035.00 MBq) +/- 10%

Substitution Permissible Dispensed as Written No Refills
Run- 1 1*B EXP: 14:15 On 10/6/2010 Unit Dose

ASSAY: 27.3865 mCi/ml 11,036.0000 MBq +/- 10% P.D. #:
NIFGR: In-House Prep LIC # :44-0073

GE Healthcare Boston Wed 10/6/2010
20 Commerce Way Woburn, MA, 01801
T: 781-932-4200 F: 781-932-4200
Old Road to Nine Acre Corner, CONCORD, MA2, 01742 MA1-047
Order# 1747099 RX# 1709510
Imaging Set / Dose by
Tc-99m Myoview (tetrofosmin)
28.00 mCi @ 11:00
Control # 37-10/6/2010

GE Healthcare Boston T: 781-932-4200
20 Commerce Way Woburn, MA, 01801 F:
Wed 10/6/2010

Tc-99m Myoview (tetrofosmin)
44.38mCi @ 7:00 On 10/6/2010
1.0224 ml (cc)
EXP: 14:15 On 10/6/2010

Order# 1747099

Nuclear Medicine A

EMERSON HOSPITAL
Tc-99m Myoview (tetrofosmin)
28.0000 mCi @ 11:00 On 10/6/2010 1.0224 ml (cc)
PT: Mackay, B 11/5/30

Imaging Set / Dose by
Myocardial Perfusion
DR: Mark Andrews Connaughton, M.D.
Control # 37-10/6/2010
P.D. #:
LIC # :44-0073

Caution To be used under the direct supervision of physician.
Product approved for use by persons licensed by the
NRC, Agreement or license permit.
ASSAY: 27.3865 mCi/ml 11,036.0000 MBq +/- 10% RX# 1709510
NIFGR: In-House Prep
Run- 1 1*B Box # 2 No Refills Unit Dose

GE Healthcare Boston Wed 10/6/2010
20 Commerce Way Woburn, MA, 01801
T: 781-932-4200 F: 781-932-4200
Old Road to Nine Acre Corner, CONCORD, MA2, 01742 MA1-047
Order# 1747099 RX# 1709510
Run - 1 Box # 2
ASSAY: 27.3865 mCi/ml 11,036.0000 MBq +/- 10%
EXP: 14:15 On 10/6/2010
NIFGR: In-House Prep
Myocardial Perfusion

EMERSON HOSPITAL
Tc-99m Myoview (tetrofosmin)
28.0000 mCi @ 11:00 On 10/6/2010 1.0224 ml (cc)
PT: Mackay, B 11/5/30

Control # 37-10/6/2010 DR: [REDACTED] M.D.
Mo-99 content < 0.15 uCi/mCi at expiration time P.D. #



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GE HEALTHCARE

011

1707.5. Patient-Centered Labels for Prescription Drug Containers

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.
 - (C) The directions for the use of the drug.
 - (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
 - (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
 - (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
 - (4) When applicable, directions for use shall use one of the following phrases:
 - (A) Take 1 [insert appropriate dosage form] at bedtime
 - (B) Take 2 [insert appropriate dosage form] at bedtime
 - (C) Take 3 [insert appropriate dosage form] at bedtime
 - (D) Take 1 [insert appropriate dosage form] in the morning
 - (E) Take 2 [insert appropriate dosage form] in the morning
 - (F) Take 3 [insert appropriate dosage form] in the morning
 - (G) Take 1 [insert appropriate dosage form] in the morning, and
Take 1 [insert appropriate dosage form] at bedtime
 - (H) Take 2 [insert appropriate dosage form] in the morning, and
Take 2 [insert appropriate dosage form] at bedtime
 - (I) Take 3 [insert appropriate dosage form] in the morning, and
Take 3 [insert appropriate dosage form] at bedtime
 - (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
 - (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
 - (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
 - (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
 - (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
 - (P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day
- (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
 - (c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
 - (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.
 - (e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.
 - (f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

EXCERPT FROM SB 1489

SEC. 25.1. Section 4076.5 of the Business and Professions Code is amended to read:

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:

(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.

(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.

(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.

(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature

the status of implementation of the prescription drug label requirements adopted pursuant to this section.

Health and Safety Code section 1250:

1250. As used in this chapter, "health facility" means any facility, place, or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, and includes the following types:

(a) "General acute care hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services. A general acute care hospital may include more than one physical plant maintained and operated on separate premises as provided in Section 1250.8. A general acute care hospital that exclusively provides acute medical rehabilitation center services, including at least physical therapy, occupational therapy, and speech therapy, may provide for the required surgical and anesthesia services through a contract with another acute care hospital. In addition, a general acute care hospital that, on July 1, 1983, provided required surgical and anesthesia services through a contract or agreement with another acute care hospital may continue to provide these surgical and anesthesia services through a contract or agreement with an acute care hospital. The general acute care hospital operated by the State Department of Developmental Services at Agnews Developmental Center may, until June 30, 2007, provide surgery and anesthesia services through a contract or agreement with another acute care hospital. Notwithstanding the requirements of this subdivision, a general acute care hospital operated by the Department of Corrections and Rehabilitation or the Department of Veterans Affairs may provide surgery and anesthesia services during normal weekday working hours, and not provide these services during other hours of the weekday or on weekends or holidays, if the general acute care hospital otherwise meets the requirements of this section.

A "general acute care hospital" includes a "rural general acute care hospital." However, a "rural general acute care hospital" shall not be required by the department to provide surgery and anesthesia services. A "rural general acute care hospital" shall meet either of the following conditions:

(1) The hospital meets criteria for designation within peer group six or eight, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982.

(2) The hospital meets the criteria for designation within peer group five or seven, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982, and has no more than 76 acute care beds and is located in a census dwelling place of 15,000 or less population according to the 1980 federal census.

(b) "Acute psychiatric hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care for mentally disordered, incompetent, or other patients referred to in Division 5 (commencing with Section 5000) or Division 6 (commencing with Section 6000) of the Welfare and Institutions **Code**, including the following basic services: medical, nursing, rehabilitative, pharmacy, and dietary services.

(c) "Skilled nursing facility" means a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis.

(d) "Intermediate care facility" means a health facility that provides inpatient care to ambulatory or nonambulatory patients who have recurring need for skilled nursing supervision and need supportive care, but who do not require availability of continuous skilled nursing care.

(e) "Intermediate care facility/developmentally disabled habilitative" means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, habilitation, developmental, and supportive health services to 15 or fewer persons with developmental disabilities who have intermittent recurring needs for nursing services, but have been certified by a physician and surgeon as not requiring availability of continuous skilled nursing care.

(f) "Special hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical or dental staff that provides inpatient or outpatient care in dentistry or maternity.

(g) "Intermediate care facility/developmentally disabled" means a facility that provides 24-hour personal care, habilitation, developmental, and supportive health services to persons with developmental disabilities whose primary need is for developmental services and who have a recurring but intermittent need for skilled nursing services.

(h) "Intermediate care facility/developmentally disabled-nursing" means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have intermittent recurring needs for skilled nursing care but have been certified by a physician and surgeon as not requiring continuous skilled nursing care. The facility shall serve medically fragile persons with developmental disabilities or who demonstrate significant developmental delay that may lead to a developmental disability if not treated.

(i) (1) "Congregate living health facility" means a residential home with a capacity, except as provided in paragraph (4), of no more than 12 beds, that provides inpatient care, including the following basic services: medical supervision, 24-hour skilled nursing and supportive care, pharmacy, dietary, social, recreational, and at least one type of service specified in paragraph (2). The primary need of congregate living health facility residents shall be for availability of skilled nursing care on a recurring, intermittent, extended, or continuous basis. This care is generally less intense than that provided in general acute care hospitals but more intense than that provided in skilled nursing facilities.

(2) Congregate living health facilities shall provide one of the following services:

(A) Services for persons who are mentally alert, persons with physical disabilities, who may be ventilator dependent.

(B) Services for persons who have a diagnosis of terminal illness, a diagnosis of a life-threatening illness, or both. Terminal illness means the individual has a life expectancy of six months or less as stated in writing by his or her attending physician and surgeon. A "life-threatening illness" means the individual has an illness that can lead to a possibility of a termination of life within five years or less as stated in writing by his or her attending physician and surgeon.

(C) Services for persons who are catastrophically and severely disabled. A person who is catastrophically and severely disabled means a person whose origin of disability was acquired through trauma or nondegenerative neurologic illness, for whom it has been determined that active rehabilitation would be beneficial and to whom these services are being provided. Services offered by a congregate living health facility to a person who is catastrophically disabled shall include, but not be limited to, speech, physical, and occupational therapy.

(3) A congregate living health facility license shall specify which of the types of persons described in paragraph (2) to whom a facility is licensed to provide services.

(4) (A) A facility operated by a city and county for the purposes of delivering services under this section may have a capacity of 59 beds.

(B) A congregate living health facility not operated by a city and county servicing persons who are terminally ill, persons who have been diagnosed with a life-threatening illness, or both, that is located in a county with a population of 500,000 or more persons may have not more than 25 beds for the purpose of serving persons who are terminally ill.

(C) A congregate living health facility not operated by a city and county serving persons who are catastrophically and severely disabled, as defined in subparagraph (C) of paragraph (2) that is located in a county of 500,000 or more persons may have not more than 12 beds for the purpose of serving persons who are catastrophically and severely disabled.

(5) A congregate living health facility shall have a noninstitutional, homelike environment.

(j) (1) "Correctional treatment center" means a health facility operated by the Department of Corrections and Rehabilitation, the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, or a county, city, or city and county law enforcement agency that, as determined by the state department, provides inpatient health services to that portion of the inmate population who do not require a general acute care level of basic services. This definition shall not apply to those areas of a law enforcement facility that houses inmates or wards that may be receiving outpatient services and are housed separately for reasons of improved access to health care, security, and protection. The health services provided by a correctional treatment center shall include, but are not limited to, all of the following basic services: physician and surgeon, psychiatrist, psychologist, nursing, pharmacy, and dietary. A correctional treatment center may provide the following services: laboratory, radiology, perinatal, and any other services approved by the state department.

(2) Outpatient surgical care with anesthesia may be provided, if

the correctional treatment center meets the same requirements as a surgical clinic licensed pursuant to Section 1204, with the exception of the requirement that patients remain less than 24 hours.

(3) Correctional treatment centers shall maintain written service agreements with general acute care hospitals to provide for those inmate physical health needs that cannot be met by the correctional treatment center.

(4) Physician and surgeon services shall be readily available in a correctional treatment center on a 24-hour basis.

(5) It is not the intent of the Legislature to have a correctional treatment center supplant the general acute care hospitals at the California Medical Facility, the California Men's Colony, and the California Institution for Men. This subdivision shall not be construed to prohibit the Department of Corrections and Rehabilitation from obtaining a correctional treatment center license at these sites.

(k) "Nursing facility" means a health facility licensed pursuant to this chapter that is certified to participate as a provider of care either as a skilled nursing facility in the federal Medicare Program under Title XVIII of the federal Social Security Act or as a nursing facility in the federal Medicaid Program under Title XIX of the federal Social Security Act, or as both.

(l) Regulations defining a correctional treatment center described in subdivision (j) that is operated by a county, city, or city and county, the Department of Corrections and Rehabilitation, or the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, shall not become effective prior to, or if effective, shall be inoperative until January 1, 1996, and until that time these correctional facilities are exempt from any licensing requirements.

(m) "Intermediate care facility/developmentally disabled-continuous nursing (ICF/DD-CN)" means a homelike facility with a capacity of four to eight, inclusive, beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have continuous needs for skilled nursing care and have been certified by a physician and surgeon as warranting continuous skilled nursing care. The facility shall serve medically fragile persons who have developmental disabilities or demonstrate significant developmental delay that may lead to a developmental disability if not treated. ICF/DD-CN facilities shall be subject to licensure under this chapter upon adoption of licensing regulations in accordance with Section 1275.3. A facility providing continuous skilled nursing services to persons with developmental disabilities pursuant to Section 14132.20 or 14495.10 of the Welfare and Institutions **Code** shall apply for licensure under this subdivision within 90 days after the regulations become effective, and may continue to operate pursuant to those sections until its licensure application is either approved or denied.



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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 22, 2011

To: Enforcement Committee

Subject: Agenda Item 2- Recommendations to Implement Regulations from the Substance Abuse Coordinating Committee, Pursuant to SB 1441

In 2008, SB 1441 (Ridley-Thomas, Chapter 548) directed that the Department of Consumer Affairs establish standardized parameters for substance abusing licensees on probation or those in monitoring programs such as the board's Pharmacists Recovery Program. These standards were developed in January 2010, and have been discussed at several board meetings.

To place the standards into effect, the board needs to adopt the standards as regulations.

After the February 2011 Board Meeting, President Weisser appointed himself and Tappan Zee to a subcommittee to work on developing the proposed regulations to implement the SB 1441 standards. The subcommittee met on March 11, and developed the language on the following pages for the board's regulations.

At this meeting, the committee needs to review each recommendation of the subcommittee, and prepare a finalized set of proposed regulation specifications.

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by
Department of Consumer Affairs,
Substance Abuse Coordination Committee



Brian J. Stiger, Director
April 2010



Substance Abuse Coordination Committee

Brian Stiger, Chair
Director, Department of Consumer Affairs

Elinore F. McCance-Katz, M.D., Ph. D.
CA Department of Alcohol & Drug Programs

Janelle Wedge
Acupuncture Board

Kim Madsen
Board of Behavioral Sciences

Robert Puleo
Board of Chiropractic Examiners

Lori Hubble
Dental Hygiene Committee of CA

Richard De Cuir
Dental Board of California

Joanne Allen
Hearing Aid Dispensers

Linda Whitney
Medical Board

Heather Martin
Board of Occupational Therapy

Mona Maggio
Board of Optometry

Donald Krpan, D.O.
Osteopathic Medical Board/Naturopathic Medicine

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Board of Pharmacy,

Steve Hartzell
Physical Therapy Board

Elberta Portman
Physician Assistant Committee

Jim Rathlesberger
Board of Podiatric Medicine

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Annemarie Del Mugnaio
Speech-Language Pathology & Audiology Board

Susan Geranen
Veterinary Medical Board

Teresa Bello-Jones
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Amy Edelen, Veterinary Medical Board
Marilyn Kimble, Board of Vocational Nursing & Psychiatric Technicians

Table of Contents

Uniform Standard #1 4

Uniform Standard #2 6

Uniform Standard #3 7

Uniform Standard #4 8

Uniform Standard #5 9

Uniform Standard #6 10

Uniform Standard #7 11

Uniform Standard #8 13

Uniform Standard #9 14

Uniform Standard #10 15

Uniform Standard #11 17

Uniform Standard #12 18

Uniform Standard #13 19

Uniform Standard #14 23

Uniform Standard #15 24

Uniform Standard #16 25

#1 SENATE BILL 1441 REQUIREMENT

Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

#1 Uniform Standard

If a healing arts board orders a licensee who is either in a diversion program or whose license is on probation due to a substance abuse problem to undergo a clinical diagnosis evaluation, the following applies:

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:
 - holds a valid, unrestricted license, which includes scope of practice to conduct a clinical diagnostic evaluation;
 - has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,
 - is approved by the board.
2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.
3. The clinical diagnostic evaluation report shall:
 - set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;
 - set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,
 - set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

Uniform Standards

April 2010

For all evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator **completes the evaluation.** ~~is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.~~

#2 SENATE BILL 1441 REQUIREMENT

Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

1. The Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.

2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested ~~at least two (2) times per week.~~

After reviewing the results of the clinical diagnostic evaluation, ~~and the criteria below,~~ a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice **based upon:** ~~However, no licensee shall be returned to practice until he or she has at least 30 days of negative drug tests.~~

- the license type;
- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the scope and pattern of use;
- the treatment history;
- the licensee's medical history and current medical condition;
- the nature, duration and severity of substance abuse, and
- whether the licensee is a threat to himself/herself or the public.

#3 SENATE BILL 1441 REQUIREMENT

Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following drug testing standards shall apply to each licensee subject to drug testing:

1. Licensees shall be randomly drug tested ~~at least 104 times per year for the first year and at any time as directed by the board. After the first year, licensees, who are practicing, shall be randomly drug tested at least 50 times per year, and at any time as directed by the board.~~
2. Drug testing may be required on any day, including weekends and holidays.
3. The scheduling of drug tests shall be done on a random basis, preferably by a computer program.
4. Licensees shall be required to make daily contact to determine if drug testing is required.
5. Licensees shall be drug tested on the date of notification as directed by the board.
6. Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.
7. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.
8. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.
9. Collection of specimens shall be observed.
10. Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.
11. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

#5 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

#5 Uniform Standard

If **the a** board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration to the following:

- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the recommendation of the clinical evaluator;
- the scope and pattern of use;
- the licensee's treatment history; and,
- the nature, duration, and severity of substance abuse.

Group Meeting Facilitator **must be approved by the board. General Qualifications and Requirements:**

1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.
2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years.
3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.
4. The facilitator shall report any unexcused absence within 24 hours.

#6 SENATE BILL 1441 REQUIREMENT

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

#7 Uniform Standard

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

1. The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
2. The worksite monitor's license scope of practice **should** ~~shall~~ include the scope of practice of the licensee that is being monitored or be another health care professional if no monitor with like practice is available.
3. ~~The worksite monitor shall have an active unrestricted license, with no disciplinary action within the last five (5) years.~~
4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
5. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.

Reporting by the worksite monitor to the board shall be as follows:

1. ~~Any suspected~~ substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If **the** occurrence is not during the board's normal business hours, the verbal report must ~~occur by~~ be made ~~within one (1) hour of~~ the next business day. A written report shall be submitted to the board within **three business days** ~~48 hours~~ of **the** occurrence.
2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

A licensee shall notify the board within 48 hours of the administration of, or the dispensing of, any prescription drug and shall provide the board with medical documentation upon request.

When a licensee tests positive for a banned substance, as determined by the board:

1. The board shall order the licensee to cease practice;
2. The board shall contact the licensee and instruct the licensee to leave work; and
3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;
2. Communicate with the licensee and/or any physician who is treating the licensee; and
3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test, **not prescribed by a licensed prescriber**, is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a “deferred prosecution” stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Failure to obtain biological testing for substance abuse;
7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. Licensee will be ordered to cease practice.
 - a) the licensee must undergo a new clinical diagnostic evaluation, and
 - b) the licensee must test negative for at least a month of continuous drug testing before being allowed to go back to work.
2. Termination of a contract/agreement.
3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to:

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

“Petition” as used in this standard is an informal request as opposed to a “Petition for Modification” under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.
2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee’s substance abuse.
3. ~~Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.~~

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

“Petition for Reinstatement” as used in this standard is an informal request (petition) as opposed to a “Petition for Reinstatement” under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
2. Demonstrated successful completion of recovery program, if required.
3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
4. Demonstrated that he or she is able to practice safely.
5. ~~Continuous sobriety for three (3) to five (5) year.~~

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.
2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors shall be compliant with all standards as set forth herein. ~~is as follows:~~

~~Specimen Collectors:~~

- ~~a) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.~~
- ~~b) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.~~
- ~~c) The provider or subcontractor must provide collection sites that are located in areas throughout California.~~
- ~~d) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.~~
- ~~e) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.~~
- ~~f) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.~~

- ~~g) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.~~
- ~~h) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.~~
- ~~i) Must undergo training as specified in Uniform Standard #4 (6).~~

~~Group Meeting Facilitators:~~

~~A group meeting facilitator for any support group meeting:~~

- ~~a) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;~~
- ~~b) must be licensed or certified by the state or other nationally certified organization;~~
- ~~c) must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years;~~
- ~~d) shall report any unexcused absence within 24 hours to the board, and,~~
- ~~e) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.~~

~~Work Site Monitors:~~

~~1. The worksite monitor must meet the following qualifications:~~

- ~~a) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.~~
- ~~b) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional, if no monitor with like practice is available.~~
- ~~c) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.~~

- ~~d) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.~~
- ~~2. The worksite monitor must adhere to the following required methods of monitoring the licensee:~~
 - ~~a) Have face to face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.~~
 - ~~b) Interview other staff in the office regarding the licensee's behavior, if applicable.~~
 - ~~c) Review the licensee's work attendance.~~
- ~~3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.~~
- ~~4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:~~
 - ~~• the licensee's name;~~
 - ~~• license number;~~
 - ~~• worksite monitor's name and signature;~~
 - ~~• worksite monitor's license number;~~
 - ~~• worksite location(s);~~
 - ~~• dates licensee had face to face contact with monitor;~~
 - ~~• staff interviewed, if applicable;~~
 - ~~• attendance report;~~
 - ~~• any change in behavior and/or personal habits;~~
 - ~~• any indicators that can lead to suspected substance abuse.~~

~~Treatment Providers~~

- ~~1. Treatment facility staff and services must have:~~
 - ~~a) Licensure and/or accreditation by appropriate regulatory agencies;~~
 - ~~b) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;~~
 - ~~c) Professional staff who are competent and experienced members of the clinical staff;~~

~~d) Treatment planning involving a multidisciplinary approach and specific aftercare plans;~~

~~e) Means to provide treatment/progress documentation to the provider.~~

2. The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:

a) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.

b) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.

c) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

~~The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.~~

- ~~• Licensee's name;~~
- ~~• Whether the licensee's practice is restricted, or the license is on inactive status;~~
- ~~• A detailed description of any restriction imposed.~~

Disclosure of information shall be governed by statute.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted ~~at least once every three (3) years~~ by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs. **The costs of such audit will be borne by the vendor.**
2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. ~~The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle.~~ The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.
3. The **vendor** ~~board and the department~~ shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

~~The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.~~

- ~~At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.~~

- ~~At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.~~



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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 22, 2011

To: Enforcement Committee

Subject: Agenda Item 3- Compounding Questions and Answers

At the June 2010 Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July 2010.

Since June, the answers to these and other submitted questions have been compiled into a document and are available on the board's Web site. The board is responding to these questions to aid pharmacies in complying with the new requirements.

The questions and concerns voiced with the regulations have not occurred really since last summer. Nevertheless, during this portion of the meeting, Supervising Inspector Ratcliff will accept and answer additional questions if they are posed.



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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 22, 2011

To: Enforcement Committee

Subject: Agenda Item 4- Enforcement Statistics and Performance Standards

The following pages provide the board's enforcement statistics for the quarter.

Additionally at the Enforcement Committee Meeting, staff will distribute the second quarter's reporting on the DCA's enforcement performance measures. The department developed the reporting parameters for this report, and the board has just amended some of its definitions to better fit DCA's definitions.

Board of Pharmacy Enforcement Statistics Fiscal Year 2010/2011

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 10/11**

Complaints/Investigations

Received	565	592	388		1545
Closed	754	632	365		1751
Pending (at the end of quarter)	1151	1229	1196		1196

Cases Assigned & Pending (by Team)

Compliance Team	394	324	393		393
Drug Diversion/Fraud	98	121	119		119
Probation/PRP	85	82	62		62
Mediation/Enforcement	74	14	9		9
Criminal Conviction	475	518	458		458

Application Investigations

Received	181	217	77		475
Closed					
Approved	85	147	120		352
Denied	23	31	17		71
Total*	150	251	205		606
Pending (at the end of quarter)	448	432	297		297

Letter of Admonishment (LOA) / Citation & Fine

LOAs Issued	65	36	34		135
Citations Issued	307	293	143		743
Citations Closed	339	358	199		896
Total Fines Collected**	\$191,990.00	\$316,395.00	\$192,210.00		\$700,595.00

* This figure includes withdrawn applications.

** Fines collected (through 02/28/2011 and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics

Fiscal Year 2010/2011

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 10/11**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	104	97	48		249
Pleadings Filed	82	65	44		191
Pending					
Pre-accusation	179	197	208		208
Post Accusation	254	271	261		261
Total*	508	496	516		516
Closed**					
Revocation					
Pharmacist	2	1	1		4
Pharmacy	0	0	0		0
Other	17	28	27		72
Revocation, stayed; suspension/probation					
Pharmacist	5	2	6		13
Pharmacy	0	0	0		0
Other	0	0	2		2
Revocation, stayed; probation					
Pharmacist	2	3	2		7
Pharmacy	1	2	4		7
Other	1	3	6		10
Suspension, stayed; probation					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	0		0
Surrender/Voluntary Surrender					
Pharmacist	2	1	2		5
Pharmacy	1	1	1		3
Other	12	8	5		25
Public Reproval/Reprimand					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	0		0
Cost Recovery Requested	\$108,566.50	\$117,558.50	\$174,152.25		\$401,277.25
Cost Recovery Collected	\$38,755.24	\$74,313.04	\$91,532.73		\$204,601.01

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics Fiscal Year 2010/2011

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 10/11**

Probation Statistics

Licenses on Probation

Pharmacist	99	103	104		104
Pharmacy	8	11	14		14
Other	27	30	34		34
Probation Office Conferences	51	26	33		110
Probation Site Inspections	36	53	41		130
Probationers Referred to AG for non-compliance	1	0	4		5

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 02/28/2011)

Program Statistics

In lieu of discipline	1	0	0		1
In addition to probation	3	3	0		6
Closed, successful	0	6	3		9
Closed, non-compliant	1	0	0		1
Closed, other	2	1	0		3
Total Board mandated Participants	45	55	45		45
Total Self-Referred Participants*	30	22	29		29
Treatment Contracts Reviewed	73	61	42		176

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of February 28, 2011